CLINICAL LABORATORY BULLETIN

February 2004

Web page: http://health.utah.gov/els/labimp

INTRODUCING:

Steven Butala	Chemistry
Krista Clayson	Virology
Mary Lou Dissel	Client Services
Paul Ince	Microbiology
Russ Shamo	Toxicology
Hannah Willcowske	Chemistry

NOTEWORTHY

Medicare Covers Immunoassay Fecal Occult Blood Colorectal Screening: Previously, the immunoassay method of screening feces for blood was covered by Medicare only if the patient had colorectal disease symptoms. General screening coverage was for guaiac testing only. Now screening patients by either method, or both, will be reimbursed.

Pre-natal Screening for Group B Strep Disease: CDC guidelines published in August of 2002 [MMWR 2002;51 (RR-11)] state all pregnant women should have a culture based screening for Group B Streptococcus (GBS) before delivery. GBS is estimated to cause 1600 cases of early onset disease in newborns and 80 deaths each year. Giving antibiotics to newborns whose mothers are colonized with GBS practically eliminates morbidity and mortality. While culturing urine is easier, it may not be as effective as vaginal/ rectal cultures for finding GBS infected mothers.

At least 10% of the GBS isolates will not have the characteristic beta hemolytic colonies. Bacteriology labs will need to know they are looking for GBS in a pre-natal culture.

FDA approved DNA based diagnostic testing has been available since November 2002 and can be completed in one hour. DCL Medical Laboratories in Indianapolis has such a test.

INR Influenced by ISI Value:
Dorothy M. Adcock, MD responded to a question in the December 2003 issue of *CAP Today* regarding the maximum International Sensitivity Index (ISI) number a lab should look for in their thromboplastin reagent. Dr. Adcock feels the CAP recommendation that laboratories use thromboplastin with an ISI between 0.9 and 1.7 (the closer to 1.0 the better) is validated by proficiency test comparative results.

Dr. Adcock further cautions laboratories to use a thromboplastin with an ISI value specific to their instrument; determine the mean normal prothrombin time (PT) for each new thromboplastin lot; and be certain the “new”

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ISI is used in the International Normalized Ratio (INR) calculations. These measures will lessen the errors that still trouble accurate PT measurements.

Blood Draw Tube Order for Plastic Tubes: For years the National Committee for Clinical Laboratory Standards (NCCLS) has told us which order to draw blood collection tubes when multiple tests are ordered on a patient. Their standard (H3-A4) hasn't changed since 6/1998. The industry has changed. Thanks to OSHA's safer sharps directive, many manufacturers make plastic blood collection tubes. Some companies coat their plastic tubes with silica to activate coagulation. So the "standard" draw order is out the window with plastic tubes. The tube manufacturer will have to tell you how to order your tubes.

Specific Gravity Testing in Body Fluids Other Than Urine: Robert Novak, MD, from Akron, Ohio's Children's Hospital feels that a urine refractometer should not be used to determine specific gravity in peritoneal, pleural or any fluid other than urine. Dr. Novak's response in the October 2003 CAP Today concerns differentiating a transudate from an exudate body fluid by determining the protein level. Direct protein measurements in these fluids is time consuming and inaccurate. Dr. Novak suggests doing a colorimetric protein test on a chemistry analyzer. Alternately, a cell count should be useful. He gives a reference (Light RW, et al. *Ann Intern Med.*1972;77:507-513) for calculating ratios to determine if a fluid is an exudate.

Culturing for *Trichomonas vaginalis*: Trying to keep a broth culture of *Trichomonas* alive from month to month for Lab Improvement's Wet Prep course proved too much. No matter what we did, they died. In the Journal of Clinical Microbiology (2002;40.3277-3280) researchers successfully culture clinical specimens on modified Columbia agar. Two studies showed this method more sensitive than broth culture, wet prep or Gram stain. Reprints of the article are available at angelika.stary@univie.ac.at

Brucella species – Are You Ready? If you are through preparing your lab to recognize anthrax and small pox, look at *Brucella*. The recent Utah case is a reminder the organism is around naturally and could come into your bacteriology lab looking very innocent.

Brucella grows on ordinary media (sheep blood agar, chocolate, MAC) in 24 to 48 hours. The bacteria are gram negative cocco-bacilli. They are Kovac's modified oxidase positive and Christensen's urease positive. No current commercial system identifies *Brucella.* Although person to person transmission has never been documented, many laboratorians have become infected working with cultures.

For additional information, check the Utah Public Health's website at www.health.utah.gov/els/microbiology. Under the Bioterrorism Response bullet select "Level A Laboratory Manual for Agents for Bioterrorism".

Anti-Animal Antibody Interference: Check out the complete article by Anne Paxton in the October 2003 CAP Today. Highlights include:

Find out where your immunoassay antibody was made (rat, mouse, cow, pig, human, etc.). Some people make their own antibodies in various animals. While human anti-mouse capture most of the literature, antibodies to all the animals listed above have been found naturally occurring in humans (also horse).

Numerous studies have shown such animal antibodies giving false positive immunoassay test results. Two such studies in the *New England Journal of Medicine* and *Clinical Chemistry* showed patients with high hCGs, who all had unwanted therapies, were traced to falsely high results due to patient's antibodies directed at the immunoassay carrier antigen.

One study showed cross reactivity to the mouse immunoglobulin by naturally occurring sheep, bovine, guinea pig, pig and some rabbit antibodies.

The good news is these antibodies are too big to pass into the urine of people with healthy kidneys, so they don't affect urine immunoassays.

Olympus Microscopes – Sales and Service: Olympus America sent letters 10/14/2003 and 11/14/2003 stating they were ending their contact with Scientific Instrument Company (SIC) to sell and service their microscopes. The second letter stated SIC would be selling their existing inventory. For additional information, contact Olympus America at 887-659-6427, email them at CustomerService@olympus.com or go online www.olympusamerica.com/microscopes.

RhoGam Dosing: The standard test for circulating fetal red blood cells in maternal blood is the Kleihauer-Betke test (KB). Although a flow cytometry method for hemoglobin F has been available for several years, few laboratories using CAP proficiency testing test for maternal bleeds with it.

The literature is full of references to KB inaccuracies. The CAP HBF proficiency test evaluations show consistently better scores for the flow cytometry method labs over the KB labs. Suretech offers an instruction manual with photos and descriptions of what to look for in the KB preps. They also offer 3 levels of control. The American Association of Blood Banks (AABB) states the sooner you give Rh immune globulin (RhoGam) the less likely the mother will become Rh sensitized.

Send your fetal hemoglobin test to a reference lab that will give you the best results for your money.

FROM THE PATIENT'S CHART

"Healthy appearing decrepit 69 year old male, mentally alert but forgetful."

☆ Feature ☆

THE TROUBLE WITH CBCs

Dianne Whitlock, MT(ASCP), Utah CLIA surveyor, responded to a laboratory that has problems with their QBC instrument and hematocrit proficiency testing. Their quality control (QC) results were always "in", but proficiency test (PT) results failed. Some of her observations can apply to any CBC instrument.

When graphed QC results show a trend going higher and higher, centrifuge calibration would help. Too high a hematocrit could result from not spinning at sufficient rcf or from not spinning long enough. Check the speed and timer on the centrifuge. They change over time and with use. The centrifuge must be level. A slanted centrifuge would affect the rcf.

QC results are in and PT results are out because CAP's PT grading criteria allows 1 standard deviation (SD) while the control company allows 2 SDs for acceptability. In order to tighten your QC range, subtract the lower acceptable hematocrit limit from the higher acceptable limit. Divide the difference by 2. Use that number to determine the acceptable range. For example, the acceptable hematocrit range for one control is 26 to 32. The difference is 6. Half the difference is 3. The mean is 29. This makes the acceptable range of 3 (+/-1.5) 27.5 to 30.5. Since the machine doesn't read 0.5 increments, round to +/-2. The acceptable range is 27 to 31. While that

doesn't seem to make much difference from a range of 26 to 32, it is enough difference to show you when you are likely to be out of acceptable PT range. The range will narrow more with the high level control (which is where this problem was – too high a hematocrit on the high end).

Another problem could be following the PT providers pre-analytic instructions **exactly.** For QCB that means holding the testing tube between thumb and forefinger and rotating the complete amount of time the provider instructs to get the dye in contact with the cells that settled out during shipment. For all CBC methods, warming the specimens long enough to reach room temperature and mixing exactly as instructed are necessary because the specimens are not the same as patient samples.

When you follow the PT providers instructions exactly, you **are** treating the samples the same as patient samples. You must also follow the instrument manufacturer's instructions for the pre-analytic phase in patient specimens exactly.

If these remedies don't solve your problems, there may be something wrong with your instrument that will require manufacturer's service.

CLIA BITS

Surveyor guidelines for the final CLIA regulation are on the web at www.cms.hhs.gov/clia. They are titled New Appendix C under Current CLIA News.

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ADDITIONAL WAIVED TESTS:

° Biosys Laboratories Optima Urine Analyzer
° Enterix Insure Fecal Immunochemical Test

° Germaine Laboratories Strep AIM Tower

° Roche Diagnostics Urisys 1100 Urine Analyzer

° Metrika A1C Now for Home Use and DXR Professional Use Hemoglobin A1C Test

° SA Scientific SAS Strep A

° Quidel Quickvue Influenza A+B Test

° Advantage Diagnostics Corporation ADC Multiple Drug Test Card

° Synova Healthcare Menocheck Menopause Indicator Test

° EFK Diagnostic Hemo_Control Measurement and Hemo_Control Microcuvettes for hemoglobin

° Genosis Fertell Female Fertility Test

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WHEN A CLIA WAIVED TEST IS <u>NOT</u> WAIVED!

A recent CMS memo to CLIA surveyors noted 3 instances when an FDA approved CLIA test would **not** be waived.

1. The test is waived for one type of specimen,

but not all specimen types. For example, pregnancy tests waived for urine are **not** waived for serum. A test waived for whole blood samples may not be waived for serum samples. Other examples include tests for mononucleosis, *H. pylori*, *B. burgdorferi* and group A Strep. Read the package insert carefully. You must have a Certificate of

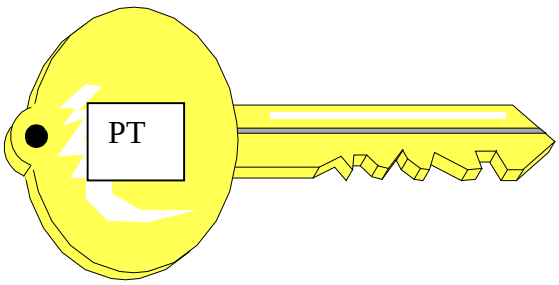
Compliance or Accreditation to perform the moderately complex version of such a test.

2. The test system has different QC requirements for waived versus moderately complex status. The only test in this category so far is the Roche CoaguChek. If you have a Certificate of Waiver or PPM, make certain you are doing the extra controls required to make this test waived. For moderate complexity this same test has different QC, personnel and proficiency test requirements.

3. The test instrument may have some analytes that are not waived when tested on it. The only instrument in this category so far is the Bayer DCA 2000+ Analyzer. If you do HgbA1C on this analyzer, it is a waived test. The analyzer can also do urine creatinine and urine micro-albumin. These two tests are **not** waived on this instrument.

Equals

"453.6 graham crackers = 1 pound cake"



CAP offers 16 new modules and has enhanced Surgical Pathology and Transfusion Medicine. For additional information check their website at www.cap.org.

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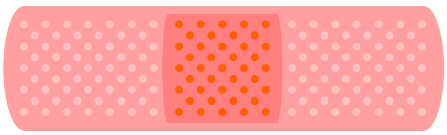
Wisconsin State added 4 new modules to their proficiency testing menu: MRSA / VRE; Group B Strep Culture; *Clostridium difficile* toxin; and Molecular Methods (for *B. pertussis*, *Herpes simplex* virus [HSV], and enterovirus). Call them at 1-800-462-5261 for a brochure.



SAFETY

Recall Notice: FDA posted a Class I recall for the VIDAS Chlamydia Assay Marketed by bioMerieux in Durham, NC. A bovine serum albumin, contained in the reagent strip, is causing accelerated degradation and creating potentially false negative results. You can find the entire recall notice at http://www.fda.gov/medwatch/SAFETY/2003/safety03.htm#vidas.

"Only those who risk going too far will ever know how far they can go." Unknown

CONTINUING EDUCATION

UDOH / BLI LENDING LIBRARY

- U-85 Packaging & Shipping of Laboratory Specimens by the Alabama Department of Health and the NLTN. Satellite broadcast video, 2.5 hrs (0.2 CDC CEUs available).

- U-86 Chemical Terrorism Preparedness: The Basics by NLTN, WSLH, UHL and MDH. Satellite broadcast video, 2.5 hrs.

1999 British GCSE exam results from 16 year olds:

Q: What does the word "benign" mean?

A: Benign is what you will be after you be eight.